Rhode Island Department of Health

INSTITUTIONAL REVIEW BOARD

FOR THE

PROTECTION OF HUMAN SUBJECTS

Guidance for Submission to the IRB:

Forms
Policies
Procedures

May 2000

For information contact:

Merry Buban, IRB Administrator (401) 222-1020
Jay Buechner, PhD, IRB Chair (401) 222-2550

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RHODE ISLAND DEPARTMENT OF HEALTH
INSTITUTIONAL REVIEW BOARD ON HUMAN SUBJECTS (IRB)
PROPOSAL ABSTRACT COVER SHEET

1. IRB Application No. _____ (to be filled in by HEALTH IRB)

2. Review Requested: ( ) Exempt (see pp. 7-8)
( ) Expedited (see pp. 10-13)
( ) Full Board (see p. 14)

Note: Final determination of the type of review to be performed rests with the HEALTH IRB.

3. Date of Request: _____

4. A. Principal Investigator: _____

Affiliation: _____

Address: _____

Tel: _____ Fax: _____ Email: _____

4. B. If Principal Investigator is a student working with a faculty advisor, provide information below:

Faculty Advisor: _____

Faculty Advisor's Address: _____

Faculty Advisor's Affiliation: _____

5. Project Title: _____

6. Anticipated Number of Subjects: _____ 7. Project start date: _____ End date:_____

8. Has funding been requested? Yes ( ) No ( )

If yes, complete the following: Sponsoring Agency_____

Proposal Submission Date_____

9. Does the project involve:	Yes	No
Research on Fetuses, Pregnant Women, or Human *InVitro* Fertilization?	( )	( )
Research on Minors?	( )	( )
Research on Prisoners?	( )	( )

10. Does the project preserve:	Yes	No
Subjects' Anonymity?	( )	( )
Subjects' Confidentiality?	( )	( )

11. Identify on a separate sheet any other participants (individuals, institutions, agencies) involved in the project and provide the date IRB approval was received or requested for each. Attach other IRB approval documents and/or letters of agreement to participate, as available.

DO NOT WRITE BELOW THIS LINE

Date of Annual Review: _____

APPROVED_____**DATE**_____

RHODE ISLAND DEPARTMENT OF HEALTH
INSTITUTIONAL REVIEW BOARD ON HUMAN SUBJECTS (IRB)
APPLICATION FOR REVIEW

(Full or Expedited, see pages 10-14)

Complete all sections unless otherwise indicated. Attach continuation pages as needed.

1. Project Title:

2. Principal Investigator's Name:

   Institutional Affiliation:

   Telephone Number:

3. Sponsor of the Study:

4. Is the project eligible for expedited review? (See pages 10-12.)

   _____Yes

   _____ No

   If Yes, on what basis? (Refer to categories on pages 10-12.)

5. Principal Investigator's professional qualifications to do the research, including a description of any necessary support services and facilities:

6. What is the purpose of the project, including the expected scientific benefits to be gained by doing the project?

7. What are the potential benefits, if any, to the individual human subjects?

8. What are the results of previous related research, if any?

9. Are certain potential human subjects excluded?

_____ Yes

_____ No

If Yes, please describe criteria for inclusion/exclusion:

10. What is the justification for inclusion of the proposed subjects? Provide specific justification for inclusion of any special/vulnerable populations, i.e., fetuses, pregnant women, and human *in vitro* fertilization; prisoners; and children: (See page 15.)

11. Describe the study design, including, as needed, a discussion of the appropriateness of research methods:

12. Describe the procedures to be performed on human subjects and/or the proposed uses of personally identifiable data:

13. Describe all potential risks of harm to subjects, including those related to any proposed use of personally identifiable data: (See page 17.)

14. What are the provisions for managing adverse reactions, outcomes, or events resulting from participation in the research?

15. What provisions are being made for the protection of the human subjects' privacy?

16. Describe the Informed Consent Procedures:

A) Description of circumstances surrounding the consent procedure, including setting, subject autonomy concerns, language difficulties, vulnerable populations:

B) Protocols for “verbal informed consent” used in telephone surveys:

C) Procedures for documenting informed consent, including any procedures for obtaining assent from minors, using witnesses, translators, and document storage:

17. What are the costs to subjects for their participation in the study, if any?

18. What is the compensation to subjects for their participation, if any?

19. What provisions are being made for the protection of confidential information related to the human subjects? (See page 17.)

20. What are the procedures for protection or erasure of confidential data when the project ends?

21. Any additional information or clarifications the investigator would like to present:

ASSURANCE OF PRINCIPAL INVESTIGATOR

Principal Investigator: _____

Institutional Affiliation: _____

Project Title: _____

I CERTIFY as follows concerning the above named research proposal in which I am the principal investigator:

1) The rights and welfare of the subjects will be adequately protected.

2) Risks or discomfort (if any) to subjects have been clearly and fully presented, and it has been shown how they are outweighed by potential benefits to the individual subject or by the importance of the knowledge to be gained.

3) The informed consent of subjects will be obtained by appropriate methods, which meet the requirements of federal regulations and the IRB.

4) Any proposed changes in research activity will be reported to the IRB. Those changes may not be initiated without IRB review and approval except where necessary to eliminate apparent immediate hazard to the subjects.

5) Any unanticipated problems involving risks to human subjects or others will promptly be reported to the IRB.

6) I have reviewed and agree to comply with all federal, state, and local laws, rules, regulations, policies, and procedures related to the protection of human subjects.

Signature: _____ Date: _____
Principal Investigator

Acknowledged: _____ Date: _____
Chair, HEALTH IRB

DOES THE PROJECT INCLUDE RESEARCH INVOLVING HUMAN SUBJECTS?

The Rhode Island Department of Health (HEALTH) Institutional Review Board (IRB) is established to review the procedures for protection of human subjects in all research projects that involve HEALTH staff, data, or other resources. The principal purpose of IRB review is to assure that the procedures for obtaining informed consent from human research subjects are properly established and administered.

To that end, the HEALTH IRB is mandated to review only those projects and programs that, in whole or part, meet the definition of research on human subjects, as presented in the federal regulations governing protection of human subjects (Title 45, Code of Federal Regulations, Part 46). The definitions are as follows:

"*Research* means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities." [45 CFR 46.102(d)]

"*Human subject* means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information. *Intervention* includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. *Private information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects." [45 CFR 46.102(f)]

If a project or program, or any component of a project or program, does not meet both of these definitions, it is not subject to IRB review.

It is the responsibility of the principal investigator (PI) of a project to obtain IRB review in all cases where appropriate. The PI may chose not to submit a project to the IRB if he/she believes it does not meet the federal definitions. However, the consequences of failing to obtain human subjects review of a project where it is required are such that it is advisable to submit any questionable projects for review. The chair, members, and staff of the HEALTH IRB are available to investigators for consultation on the necessity of submitting specific projects for IRB review.

RESEARCH EXEMPT FROM IRB REVIEW

Projects that do not meet the definition of research or do not involve human subjects as defined on page 7 are exempt from IRB review. For projects that meet these definitions, the following categories are exempt from review, per 45 CFR 46.101(b).

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, qualifies as exempt ***unless***:

(i) information obtained is recorded in such a manner that human subjects can be identified directly or through identifiers linked to the subjects (*information must be anonymous*); **and**
(ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph 2, if:

(i) the human subjects are elected or appointed public officials or candidates for public office, **or**
(ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects.

5. Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate or otherwise examine:

(i) public benefit or service programs;
(ii) procedures for obtaining benefits or services under those programs or procedures; or
(iii) possible changes in or alternatives to those programs or procedures; or
(iv) possible changes in methods or levels of payment for benefits or services under those programs.

6. Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

SUBMISSION OF PROPOSALS FOR EXEMPT REVIEW

If it is determined that human subjects are involved, the principal investigator shall consult with the appropriate representative of the IRB to make a preliminary determination of whether the research involved is exempt from IRB review. In situations where the principal investigator is a student, the student's faculty sponsor at the institution in which the student is enrolled shall also consult in the decision regarding exempt status. **Where it is clear that the project is in the "exempt" category, the research work may proceed *after* review by the HEALTH IRB. If the status of the project cannot be assigned from the preliminary determination by the IRB representative, the following information is required.**

In making the request for exempt review, submit:

1. A letter by the principal investigator indicating why the exemption should be granted, citing which of the six published reasons for exemption applies. (See page 8.) In the case of a student, the letter should either be written by or endorsed by the student's faculty sponsor.

2. A completed Proposal Abstract Cover Sheet and a brief project summary should be attached with one copy of the complete research proposal, including any informed consent forms to be used. If applicable, submit copies of survey forms, questionnaires, or interview questions.

3. An Assurance Form (Page 6) signed by the Principal Investigator (or, in the case of a student, the student's faculty sponsor and/or chairperson of the department).

4. If the research involves a cooperating agency, institution, school district, etc., a letter of agreement to participate in the research (on letterhead) is required. Research that is to be conducted in foreign countries requires a letter of agreement from an appropriate official or cooperating institution.

Mail or deliver all submission materials to:

Administrator
Institutional Review Board
Rhode Island Department of Health
3 Capitol Hill, Room 407
Providence, RI 02908

RESEARCH ELEGIBLE FOR EXPEDITED IRB REVIEW

Applicability

(A) Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

(B) The categories in this list apply regardless of the age of subjects, except as noted.

(C) The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

(D) The expedited review procedure may not be used for classified research involving human subjects.

(E) IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review--expedited or convened--utilized by the IRB.

(F) Categories one (1) through seven (7) pertain to both initial and continuing IRB review.

Research Categories

(1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

(a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

(b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

(2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

(a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

(b) from other adults and children[2], considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

(3) Prospective collection of biological specimens for research purposes by noninvasive means.

Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

(4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

(5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects, 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

(6) Collection of data from voice, video, digital, or image recordings made for research purposes.

(7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the

protection of human subjects, 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

(8) Continuing review of research previously approved by the convened IRB as follows:

(a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or

(b) where no subjects have been enrolled and no additional risks have been identified; or

(c) where the remaining research activities are limited to data analysis.

(9) Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

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[1] An expedited review procedure consists of a review of research involving human subjects by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the requirements set forth in 45 CFR 46.110.

[2] Children are defined in the HHS regulations as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted." 45 CFR 46.402(a).

Source: 63 Federal Register 60364-60367, November 9, 1998.

SUBMISSION OF PROPOSALS FOR EXPEDITED IRB REVIEW

If the proposal might qualify for expedited review, the principal investigator must submit two (2) copies of the complete research proposal*, less any appended material not necessary to an understanding of the project, plus two (2) copies of a package containing the following:

A. "Proposal Abstract Cover Sheet" (Page 1) with required information provided

B. A completed "Application for Review" (Pages 2-5)

C. A signed "Assurance of the Principal Investigator" (Page 6)

D. An "Informed Consent" statement (form) written in language comprehensible to the subject, if applicable (Pages 18-20)

E. If the research involves a cooperating agency, institution, school district, etc.; a letter of agreement to participate in the research (on letterhead) is required. Research that is to be conducted in foreign countries requires a letter of agreement from an appropriate official or cooperating institution.

*If the proposal is part of a thesis, dissertation, or sponsored research grant proposal, two (2) copies of that proposal should also be submitted.

Completed applications will be submitted to the IRB Administrator. The Chair of the IRB or a designated experienced IRB member will review the application and prepare a report of action, indicating the outcome of the review. A minimum of two weeks will be needed to perform an expedited review.

Mail or deliver all submission materials to:

Administrator
Institutional Review Board
Rhode Island Department of Health
3 Capitol Hill, Room 407
Providence, RI 02908

SUBMISSION OF PROPOSALS FOR FULL IRB REVIEW

If neither exempt nor expedited review is permitted, the IRB will require from the principal investigator two (2) copies of the complete research proposal*, less any appended material not necessary to an understanding of the project, plus fourteen (14) copies of a package containing:

A. "Proposal Abstract Cover Sheet" (Page 1) with required information provided

B. A completed "Application for Review" (Pages 2-5)

C. A signed "Assurance of the Principal Investigator" (Page 6)

D. An "Informed Consent" statement (form) written in language comprehensible to the subject, if applicable (Pages 18-20)

E. If the research involves a cooperating agency, institution, school district, etc.; a letter of agreement to participate in the research (on letterhead) is required. Research that is to be conducted in foreign countries requires a letter of agreement from an appropriate official or cooperating institution.

*If the proposal is part of a thesis, dissertation, or sponsored research grant proposal, two (2) copies of that proposal should also be submitted.

Completed applications will be submitted to the IRB Administrator. The IRB Chair will assign one principal reviewer for each proposal. Each member of the IRB will have a proposal abstract, Application Form, and associated materials for review. The principal investigator could be asked to clarify relevant issues, attend the IRB meeting or submit additional materials. The principal investigator is encouraged to attend the IRB review meeting, which are regularly scheduled at approximately two-month intervals.

At the IRB meeting following the initial review, the principal reviewer will present the proposal to the Board with his/her recommendations. Following a discussion of the proposal, the Board will determine the disposition of the proposal.

Mail or deliver all submission materials to:

Administrator
Institutional Review Board
Rhode Island Department of Health
3 Capitol Hill, Room 407
Providence, RI 02908

RESEARCH INVOLVING HUMAN SUBJECTS WHO ARE AFFORDED SPECIAL PROTECTIONS

Certain categories of human research subjects are afforded special protections under federal regulations because they are at greater risk of adverse consequences and/or because they require special consideration in the informed consent process. These categories are -

(1) Fetuses, pregnant women, and human *in vitro* fertilization
(2) Prisoners
(3) Children

The special protections afforded each of these categories of human subjects are detailed in Subparts B, C, and D of the federal regulations regarding the protection of human subjects, 45 CFR 46. Investigators submitting projects involving one or more of these groups must identify on the Proposal Abstract Cover Sheet which group(s) are involved and include in their submissions to the IRB (1) a justification for choosing to include these subjects, (2) information on the possible risks for these subjects, and (3) a description of any special procedures or forms to be used with these subjects in the informed consent process.

[Note: The National Institutes of Health (NIH) have instituted policies supporting diversity in the selection of human research subjects, for the purpose of maximizing the applicability of research results to all relevant populations. Investigators performing NIH-sponsored research projects should be aware of these policies and, for some groups, the impact of the policies on informed consent procedures. The policies are "Inclusion of Children in Research" and "Inclusion of Women and Minorities in Research" and can be found at the NIH web site "grants.nih.gov/grants/oprr/library_human.htm" under the heading "National Institutes of Health (NIH) Information."]

MINORS AS RESEARCH PARTICIPANTS

Children are more vulnerable than other research participants "...because of their more limited cognitive competencies and experiential backgrounds, which constrain their capacities to understand and defend their rights as research participants and to make responsible decisions concerning research participation. They are also vulnerable because of their limited social power, which impairs their ability to exercise independent decision making concerning research participation..." (Thompson, 1990). Because of these limitations, special caution is advised in the preparation and review of protocols involving children as subjects. These include:

Consideration of the developmental level of the individual in the determination of "minimal risk": It is usually assumed that vulnerability in children decreases with age. However, there are conditions in which vulnerability increases or peaks at certain ages. For example, children's increasing self awareness or adolescents' sensitivity to their changing bodies may make older children more vulnerable than younger children.

Considerations in obtaining informed consent or assent: It is clear that consent is required from the parent or guardian. Less clear are the requirements for the child's assent. Although children cannot consent to research, they do have the right to refuse to participate. It is recommended that the following be delineated in obtaining assent from children:

1. That assent be required and obtained in writing from the child unless there is a clear, written justification for not obtaining assent.

2. That there be a clear means of documenting how assent is obtained, and by whom. Where appropriate, a separate form should be drafted with language appropriate to the child's developmental level.

Explanation of and process for quitting or withdrawal from the research: Since children tend to be acquiescent to adult wishes and are often reluctant to speak up when uncomfortable, special attention must be given to processes for quitting or withdrawal from research. Along with the usual statements in the informed consent form, the researcher is advised to:

1. Be cognizant of signs of discomfort shown by the child throughout the interview or testing procedures, and periodically inquire about the child's reactions or feelings.

2. Include procedures for withdrawal that address the above considerations.

CONFIDENTIALITY AND RESEARCH RISK

Many research proposals submitted to the HEALTH Institutional Review Board involve use of personally identifiable confidential information in the Department's databases, with no intent to contact the individuals whose information is being used. These proposals may be eligible for exemption from informed consent requirements or review under the expedited procedure. Such proposals should address the following issues in their IRB submissions:

Determine whether the proposed use of the data is research on human subjects as defined in the federal regulations governing human subjects protection. (See page 7.)

Specify the risks and benefits of participating in the research for the human subjects.

> Very often, there are no direct benefits to individuals whose confidential data is accessed.
>
> Risks may often include inadvertent and purposeful release of confidential data on an individual. Such release may occur through release of sufficient descriptive information as to allow identification, even when no identifiers are released.

Minimize the risks to human subjects in the design and conduct of the research. For use of existing data, this means that -

> The minimum amount of confidential information is requested that is necessary to perform the research.
>
> The information is accessible to and handled by the minimum number of personnel possible.
>
> Identifiers are removed from the database or the database is returned to the owner as soon as no longer needed.
>
> Data that are published or otherwise released are aggregated so that no individual can be identified either directly or indirectly through knowledge of non-confidential data items.

Specify measures to protect data when on computers and when stored on electronic media. Also describe any data linkages that would result in anonymous data becoming identifiable to an individual.

If any contact is proposed with an individual identified through access to a HEALTH database, the issues of informed consent become relevant, and all protocols and forms must be reviewed in addition to measures to protect confidentiality.

GENERAL REQUIREMENTS FOR THE INFORMED CONSENT STATEMENT

1. Informed consent must be obtained only under such circumstances that provide the prospective subject, or the subject's representative, sufficient opportunity to consider participation in the research project and where the possibility of coercion or undue influences is minimized.

2. The Informed Consent Statement

   a. must be written in language understandable to the subject or representative;

   b. shall not contain any language by which the subject waives any of his or her rights;

   c. shall not contain any language that releases the principal investigator or the sponsoring agency from liability for negligence;

   d. should include a statement such as, "you are over 18 years of age," if appropriate.

3. The Informed Consent Statement should follow the format and outline given on the next page, as appropriate. When the subject is a minor and the parent's or guardian's consent is sought, space for the parent's or guardian's signature should be provided. If the subject is an adult requiring guardian consent, space for the guardian's signature should be provided. Alternatively, where it is necessary to separate the consent of the parent/guardian from the assent of the minor or non-consenting adult, separate forms should be used for each.

4. Two copies of the Informed Consent statement must be signed; one copy is to be retained by the individual (or his/her representative/guardian), and one copy is to be kept by the principal investigator. (NOTE: the signature page may not be completely separated from the text of the informed consent.)

N.B. For further guidance, see the "Informed Consent Information" section on the National Institute of Health's Human Subjects Protection website. (Links to key websites are listed on page 22.)

SAMPLE INFORMED CONSENT FORM

Title of Project _____

Introductory section should begin with words to this effect:
You have been asked to take part in a research project described below. The researcher will explain the project to you in detail. You should feel free to ask questions. If you have more questions later, {Name of P.I.}, the person mainly responsible for this study, { Phone }, will discuss them with you. You must be at least 18 years old to be in this research project (if appropriate).

Description of the project:
You have been asked to take part in the study that {here describe the nature of the study and the purpose of the research}.

What will be done:
If you decide to take part in this study here is what will happen: {explanation of what will happen to the subject; how long the subject will be involved in the study; and state what portions, if any, are considered experimental. Explain alternative procedures, if any}.

Risks or discomfort:
{Explain any risks or discomfort that might reasonably be expected to happen. If there are no risks or discomforts, state that here}.

Benefits of this study:
{Describe benefits to the subject, or to others, of this study. If of no direct benefit to the subject, include a sentence to the following effect:} Although there will be no direct benefit to you for taking part in this study, the researcher may learn more about { }. (NOTE: payment given to the subject for participation in the study is not a benefit, it is a recruitment incentive.)

Confidentiality:
{Describe the way confidentiality of records identifying the subject will be maintained. Use words to the following effect, if appropriate:} Your part in this study is confidential. No information will be released that identifies you by name. All records will {describe how records are to be maintained}.
{Or, if the study involves information that legally must be reported to government agencies, then include the following:} My part in this study is confidential within legal limits. The researchers and the sponsoring agency will protect your privacy, unless they are required by law to report information to city, state or federal authorities, or to give information to a court of law. Otherwise, none of the information will identify you by name. All records will be {describe how they are to be maintained}.
{Alternatively, if the study is anonymous, then this should be stated here. Indicate to the subject how anonymity will be preserved.}

In case there is any injury to the subject: (If applicable)
{Explain whether any medical or other treatment is available if injury occurs, and who to contact; use words to this effect:} If this study causes you any injury, medical treatment will be provided to you through { }, and this treatment will be paid for by { }. To report any injury that happens because you agreed to be in this study, you should write or call { }.

Decision to quit at any time:
{Use words to the following effect:} The decision to take part in this study is up to you. You do not have to participate. If you decide to take part in the study, you may quit at any time. Whatever you decide will in no way {penalize you} {affect your benefits, medical care}{etc.} {insert appropriate language}. If you wish to quit, you simply inform {name and phone number of principal investigator} of your decision.

Rights and Complaints:
{Use words to the following effect:} If you have any questions later about your rights as a participant in this research, or if you are not satisfied with the way this study is performed, you may speak with {P.I.'s Name} or with {name and phone of individual}, anonymously, if you choose. In addition, you may contact { }, who is the Administrator of the Institutional Review Board of the Rhode Island Department of Health, at { }.

You have read the Consent Form. Your questions have been answered. Your signature on this form means that you understand the information and you agree to participate in this study.

_____	_____
Signature of Participant	Signature of Researcher
_____	_____
Typed/printed Name	Typed/printed name
_____	_____
Date	Date

CONSENT FORM
(*Name of Project*)

TEAR OFF AND KEEP THIS FORM FOR YOURSELF

Dear Participant:

1. You have been asked to take part in the research project described below. If you have any questions, please feel free to call (*Principal Investigator, phone number*), the person mainly responsible for this study.
2. The purpose of this study is to (*state purpose*). Responses to these items will be (*state how responses will be collected and how confidentiality will be maintained).*
3. **YOU MUST BE AT LEAST 18 YEARS OLD** to be in this research project or to consent to your child's participation.
4. If you decide to take part in this study, your participation will involve (describe procedures) pertaining to (*state appropriate information*).
5. The possible risks or discomforts of the study are minimal, although you may feel some embarrassment answering questions about private matters (*delete last phrase if it is not appropriate for your project*).
6. Although there are no direct benefits of the study, your answers will help increase the knowledge regarding (*state appropriate information*).
7. Your part in this study is confidential. That means that your answers to all questions are private. No one outside the project can know if you participated in this study or know any information about your participation. Scientific reports will be based on group data and will not identify you or any individual as being in this project.
8. The decision to participate in this research project is up to you. You do not have to participate and you may quit at any time.
9. Participation in this study is not expected to be harmful or injurious to you. However, if this study causes you any injury, you should call the "IRB Administrator" at the Rhode Island Department of Health, (401) 222-2550.

If you have any more questions or concerns about this study, you may contact _____at_____.
You are at least 18 years old. You have read the consent form and your questions have been answered to your satisfaction. Your filling out the survey implies your consent to participate in this study.
If these questions are upsetting and you want to talk, please use the phone numbers below: (*appropriate in cases where questions are of a sensitive nature*)
(*Names and phone numbers of resources available, e.g., Counseling Center, Women's Resource Center, AA, etc.*).

Thank you, (*Name of Investigator*)

MONITORING PROCEDURES

The Code of Federal Regulations empowers the Institutional Review Board (IRB) to "conduct continuing review of research at intervals appropriate to the degree of risk, but not less than once per year, and to observe or have a third party observe the consent process and the research." (45 CFR 46.109(e))

Approved projects are assigned a monitoring date. All investigators will receive a monitoring form in advance of that date that must be completed and returned to the HEALTH IRB ten days before the designated date. In addition, you will be asked to submit a copy of the *signed* consent form you most recently used (white out subject's signature to preserve confidentiality) and a summary of the project or the annual report to a funding agency.

The IRB will review these documents to ensure that your research protocol continues to be in compliance with federal and state regulations.

Continuing research must be monitored and approved for continued IRB approval. If you do not respond to our request for review within the specified time frame, your project will no longer have IRB approval.

FOR ADDITIONAL INFORMATION

For general information involving human subjects protection, see the website for the Office for Protection (OPRR) from Research Risks at the National Institutes of Health (NIH):

grants.nih.gov/grants/oprr/oprr.htm

For documents relating to human subjects protection, including -

The "Belmont Report"
Regulations for the Protection of Human Research Subjects (45 CFR 46)
Institutional Review Board Guidebook
Informed Consent Information

see the documents library at the NIH OPRR website:

grants.nih.gov/grants/oprr/library_human.htm

For guidance with human subjects protection issues in public health, see the human subjects protection website at the Centers for Disease Control and Prevention:

www.cdc.gov/od/ads/hsr2.htm

For information on federal certificates of confidentiality, which protect confidential information collected on research subjects from access through most federal, state, and local legal actions, such as subpoenas, see the following websites:

Contacts: grants.nih.gov/grants/oprr/humansubjects/guidance/cert-con.htm

Description: grants.nih.gov/grants/oprr/humansubjects/guidance/certconpriv.htm

For Rhode Island's Confidentiality of Healthcare Communications and Information Act (Rhode Island General Laws Chapter 5-37.3) and specifically for requirements relating to the release of medical records (Section 5-37.3-4(d)) see:

www.rilin.state.ri.us/Statutes/TITLE5/5-37.3/INDEX.HTM

Rhode Island Department of Health
Institutional Review Board
Operating Policies and Procedures
(As adopted October 1, 1999)

I. The Multiple Project Assurance

The Rhode Island Department of Health's Institutional Review Board ("the IRB") is established under the Multiple Project Assurance (MPA) for the protection of human subjects of research submitted to the Office for Protection from Research Risk (OPRR) of the National Institutes of Health, Public Health Service, United States Department of Health And Human Services. The MPA includes specific provisions governing the following:

The institutional authority under which the IRB is established and empowered.

The definition of the purpose of the IRB, i.e., the protection of human subjects of research.

The principles which govern the IRB in assuring that the rights and welfare of subjects are protected.

The authority of the IRB, specifically --

The scope of authority of the IRB, i.e., what types of studies must be reviewed.

The IRB's authority to disapprove, modify or approve studies based upon consideration of human subject protection aspects.

The IRB's authority to require progress reports from the investigators and oversee the conduct of the study.

The IRB's authority to suspend or terminate approval of a study.

The IRB's authority to place restrictions on a study.

II. Federal regulations for the protection of human subjects

The operations of the IRB are governed by federal regulations for the protection of human subjects, 45 Code of Federal Regulations 46 (45 CFR 46).

III. Institutional setting of the IRB

The IRB is established within the institution of the Rhode Island Department of Health under the authority of the Director of Health to submit the Multiple Project Assurance for the protection of human subjects. The Chair of the IRB reports to the Director of Health and is responsible for the administration of the IRB.

IV. Membership of the IRB

Number of members: The IRB shall have nine primary members and as many alternate members as is necessary for efficient functioning.

Qualification of members: Taken together, the members of the IRB shall possess broad competence and experience in sociological and medical research, knowledge of the community and its diverse cultures from which human research subjects are generally selected, and the ability to review proposed research in terms of relevant law, regulation, and standards of professional practice.

Diversity of members: The IRB shall include representation by (1) both men and women, (2) multiple professions, (3) scientific and non-scientific members (at least one of each), and (4) at least one member not otherwise affiliated with the Rhode Island Department of Health. Every non-discriminatory effort shall be made to include members who represent disadvantaged populations from which research subjects may be selected.

Alternate members: Alternate members shall be selected according to the same considerations as primary members. Alternate members serve in a voting capacity at those meetings where the Chair has determined that such participation is necessary for a quorum. Alternate members are also encouraged to attend and participate regularly in other IRB meetings in a non-voting capacity.

V. Management of the IRB

The chairpersons: The Chair and Vice-Chair of the IRB are invited by the Director of Health to serve for terms of no more than three years. The Chair and Vice-Chair may serve in office for two or more consecutive terms if invited. The Chair is responsible for conducting the meetings of the IRB and for administering the review of human subjects research in the Department of Health. The Vice-Chair conducts meetings of the IRB in the absence of the Chair.

The IRB members: All primary and alternate members of the IRB are invited by the Director of Health to serve for terms of no more than three years. Primary members serve terms that are staggered to maintain continuity of a majority of the membership over the end of each term. Members may serve for two or more consecutive terms if invited. Primary and alternate members are expected to attend at least half of all scheduled IRB meetings during each year of their term.

Training of IRB chair and members: Each newly appointed IRB member will be oriented to the principles of human subjects protection and the operations of the IRB by an experienced IRB member selected by the Chair. The Chair will provide new members with materials relevant to (1) the principles of informed consent and human subjects protection, (2) the federal regulations governing human subjects protection, and (3) policies and procedures of the IRB. The Chair will alert members to opportunities for professional development in the area of human subjects protection and will maintain a library of relevant reference materials.

Compensation of IRB members: The IRB does not compensate members for their service.

Liability coverage for IRB members: Members of the IRB are protected from liability arising from their IRB service by state law, when acting in good faith and in accordance with IRB policies and procedures and federal regulations.

Use of consultants: At the discretion of the Chair, the IRB may supplement the expertise of its members by inviting individuals with competence in special areas to assist in reviews of research proposals. Any member may request the Chair to obtain the assistance of such an individual.

Administrative/secretarial support staff: The Rhode Island Department of Health shall provide all administrative and secretarial support needed to administer the IRB's operations. The staff will perform their duties under the direction of the Chair.

Resources: The Rhode Island Department of Health shall provide meeting rooms, filing space, reproduction equipment, computers, etc., as needed to support the IRB's operations.

Conflict of interest: No IRB member, including the Chair, shall participate in the initial or continuing review, including discussion and voting, of any proposal in which the member has a conflicting interest, except to provide information requested by the IRB. It is the responsibility of each member to inform the Chair of such conflict prior to the review of the affected proposal.

VI. Functions of the IRB

The functions of the IRB are to –

Take steps to ensure that employees of the Department of Health are knowledgeable of the requirements for protecting human research subjects and submit all relevant research studies to the IRB for review.

Determine whether submitted proposals are exempt from human subjects review, are eligible for expedited review, or must undergo review by the full board.

Conduct initial and continuing reviews of submitted proposals that require human subjects review.

Report, in writing, findings and actions of the IRB to investigators and their institutions.

Determine which studies require continuing review more often than annually.

Determine which studies need verification from sources other than the investigators that no material changes have occurred since previous IRB review.

Take steps to ensure prompt reporting to the IRB of changes in research activities.

Take steps to ensure that changes in approved research are not initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards.

Take steps to ensure prompt reporting to the IRB, appropriate institutional officials, and OPRR of --

-unanticipated problems involving risks to subjects or others,

-serious or continuing noncompliance with 45 CFR 46 or the requirements of the IRB, and

-suspension or termination of IRB approval.

Determine which studies pose minimal risk to human subjects and which studies pose greater than minimal risk to human subjects.

VII. Operations of the IRB

Scheduling of meetings: The IRB shall schedule routine meetings at intervals of two months, the day of the week, time, and place determined according to the convenience of the members. The Chair may cancel routinely scheduled meetings or schedule additional meetings based on the number and urgency of submitted proposals to review.

Pre-meeting distribution to members: The Chair shall provide each member with the following items no later than one week prior to a scheduled meeting:

Meeting agenda, with date, time, and place of meeting and list of studies to be reviewed.

Minutes of the previous meeting.

All materials necessary for review of studies.

The review process: Upon submission of a study for IRB review, one primary reviewer, selected on a rotating basis with consideration of subject matter expertise and potential conflicts of interest, receives the complete study documentation for review, determines whether all necessary information is present, and makes a recommendation to the Chair as to whether the study is exempt from review, eligible for expedited review (see below), or requires full board review. For studies requiring full board review, the primary reviewer selects which submitted materials are needed by the full board, presents the study, presents their review based on the criteria in 45 CFR 46.111, and leads the discussion. The primary reviewer is responsible for assuring that other members have access to complete study documentation if needed during the discussion.

Expedited review procedure: The primary reviewer may recommend and perform an expedited review after determining the study's eligibility for such review under federal regulation. No study may be disapproved by expedited review, but must be referred to the full board. All IRB members will be informed of studies that are approved by expedited review at the same time as the investigator. When notified, any member of the IRB may request further consideration of a study approved under expedited review at the next scheduled IRB meeting, at which time the full

Board may choose to review the study. Investigators will be notified of this possibility at the time they receive the results of the expedited review.

Modifications to ongoing studies: Modifications to ongoing studies will in general be reviewed in the same manner (expedited/full board) as the original study, except that modifications that involve no more than minimal risk to human subjects may be reviewed on an expedited basis even when the original study was reviewed by the full board. The primary reviewer will make a recommendation to the Chair as to the manner of review of such modifications.

Voting requirements: A quorum of the IRB needed to act on a study is five primary and/or alternate members who are eligible to vote on the study, i.e., have no conflict of interest. A simple majority of those present and eligible to vote is required for approval of a study. Members may participate by conference call by prior arrangement. Only primary members or alternate members designated as voting members by the Chair may vote at an IRB meeting. Whenever possible, alternate members will be notified in advance of their designation as voting members for a specific meeting. Proxy voting on a study is not permitted.

Subsequent review: The Director of Health may disapprove a study after the IRB has reviewed and approved the study. Investigators will be notified of this possibility at the time they receive the results of the review of their study by the IRB. No one in the organization may approve a study after it has been disapproved by the IRB.

Communication from the IRB: Within one week of making a determination, either through expedited or full board review, the IRB shall communicate the results of its reviews, including findings that studies are exempt from human subjects review, to (1) the study investigator, (2) to all members of the IRB, and (3) to the Director of Health. As appropriate, the IRB will communicate the results of its reviews to the sponsors of reviewed research studies.

VIII. IRB record-keeping requirements: The following items shall be maintained in order to document IRB activities:

Current Multiple Project Assurance filed with OPRR

IRB membership roster showing qualifications

IRB operating policies and procedures

Agendas and minutes of meetings, including –
- Members, consultants, guests, and others present
- List of studies reviewed
- Summary of discussion on debated issues
- Record of IRB decisions
- Record of voting by name, showing votes for and against and abstentions

All protocols reviewed and approved consent documents

Communications to and from the IRB.

Adverse reactions reports and documentation that the IRB reviewed such reports.

Records of continuing review.

Statements of significant new findings provided to subjects

Records relating to the review of specific studies shall be maintained for at least three years after the end of the study. Records of continuing relevance, such as the MPA, *curricula vitae* of current members, etc., shall be maintained until superseded. All other records shall be maintained for three years after receipt.

IX. Submission of studies to the IRB for review: The study investigator will provide, at a minimum, the following information to the IRB for its review of human subjects protection:

The investigator's professional qualifications to do the research, including a description of any necessary support services and facilities.

The study protocol, which includes or addresses –

Title of the study

Purpose of the study, including the expected benefits to be gained by doing the study

Sponsor of the study

Results of previous related research

Subject inclusion/exclusion criteria

Justification for inclusion of the proposed subjects, with specific justification for inclusion of any special/vulnerable populations, i.e., fetuses, pregnant women, and human *in vitro* fertilization; prisoners; and children

Study design, including, as needed a discussion of the appropriateness of research methods

Description of procedures to be performed

All potential risks to subjects

Provisions for managing adverse reactions

Circumstances surrounding the consent procedure, including setting, subject autonomy concerns, language difficulties, vulnerable populations

Procedures for documenting informed consent, including any procedures for obtaining assent from minors, using witnesses, translators, and document storage

Compensation to subjects for their participation

Provisions for protection of the subject's privacy

Provisions for protection of confidential information on subjects

Extra costs to subjects for their participation in the study

The proposed informed consent document, containing all requirements of 45 CFR 46.116(a) and, as necessary, 45 CFR 46.116(b).

Any requests for changes in study after initiation, for previously reviewed studies.

Any reports of unexpected adverse events, for previously reviewed studies.

Progress reports, submitted for use in continuing review.

X. Precedence

Every attempt has been made to establish these operating policies and procedures in conformance with the Rhode Island Department of Health's Multiple Project Assurance and with Title 45 Code of Federal Regulations Part 46 (Protection of Human Subjects). Notwithstanding these policies and procedures, it is understood that the MPA and 45 CFR 46 take precedence.

XI. Adoption and amendment

These Operating Policies and Procedures stand as approved by the Institutional Review Board of the Rhode Island Department of Health at the meeting of October 1, 1999. They may be amended as needed by a majority vote at any subsequent IRB meeting. All amended policies and procedures so adopted will become effective as of the next following meeting of the IRB.